WALTER REED ARMY INSTITUTE OF RESEARCH
DIVISION OF VIRAL DISEASES

Surveillance of Influenza and Other Respiratory Disease in US Embassy Personnel

Packaging and Shipping of Biological Substances Procedures

28 JULY 2008

1.0 BACKGROUND

The regulations governing the transport of dangerous goods (i.e., Infectious Substances) by air are published by the International Civil Aviation Organization (ICAO). These technical instructions are internationally agreed upon standards which are recognizable as authoritative and binding by many countries.

The International Air Transport Association (IATA) is an association of member airlines which was formed to establish standard guidelines for commercial air transport of not only dangerous goods, but many other items as well. The IATA incorporates the ICAO standards in its Dangerous Goods Regulation.

There are 9 classes of Dangerous Goods. The purpose of this document is to provide guidance in transporting those Dangerous Goods that fall under Class 6, Division 6.2, Category B (Biological Substances) and Class 9 (specifically dry ice). Category B substances include clinical or diagnostic specimens that are collected directly from humans or animals, including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluid swabs being transported for purposes such as research, diagnosis, investigational activities, disease treatment and prevention.

2.0 SUPPLIES

2.1. Absorbent materials (e.g., absorbent pads, gauze, etc.)
2.2. Air bills (e.g., World Courier®)
2.3. Biohazard labels
2.4. Bubble wrap or other shipping cushion materials
2.5. Cardboard dividers for specimen storage boxes
2.6. Cold packs
2.7. Dry ice, if applicable
2.8. Dry ice (CO_2 solid) labels (Class 9 Hazard Label; UN1845), if applicable
2.9. Fiberboard specimen storage boxes
2.10. Orientation labels (e.g., "This Side Up")
2.11. Proper shipping name labels (e.g., "Diagnostic Specimens; UN 3373")
2.12. Shipping or strapping tape
2.13. Styrofoam® shipping containers (UN-qualified)
2.14. Watertight Primary Containers (e.g., cryovials, swab tubes, aliquot tubes)
2.15. Watertight Secondary Containers (e.g., plastic sealable bag)

3.0 PROCEDURES

Note: Biological Substances, Category B materials are packaged in accordance

with IATA Packing Instruction (PI) 650 (see Appendix VI). In general, PI 650 requires specimens to be packed in at least three levels of containment – primary container, secondary packaging, and rigid outer packaging (shipping container).

3.1. **Required Documentations**

3.1.1 Shipping courier air bill

3.1.2 Packing list.

3.1.3 Other documentations (i.e., permits, declarations, invoices, etc.) as required by the applicable governing body of the host country.

3.2. **Packaging Specimens for Shipment at Room Temperature (RT)**

3.2.1 Ensure that each specimen vial or tube (primary container) is securely closed with screw-cap. **Note**: The maximum allowable volume of each primary container is 1L.

3.2.2 Insert the specimen vials or tubes upright into the cardboard divider in the fiberboard specimen storage box.

3.2.3 Close the fiberboard specimen storage box and secure the lid with shipping tape.

3.2.4 Place the fiberboard specimen storage box and the absorbent material in the plastic biohazardous bag (secondary packaging). Seal the biohazardous bag. **Note**: If shipping multiple specimen storage boxes, each box must be wrapped and sealed individually.

3.2.5 Place the sealed secondary package into the shipping box (outer packaging). **Note**: The total volume contained in the shipping box (i.e., total volume of all specimens) must not exceed 4L.

3.2.6 Place cold packs on each side and on top of the secondary package. **Note**: The cold packs should be kept at room temperature for at least 24 hours prior to packaging. They serve to moderate the temperature inside the shipping container.

3.2.7 Fill the shipping container completely with bubble wrap or other cushioning materials to prevent the secondary package from shifting during transit.

3.2.8 Close the lid to the Styrofoam® shipping container.

3.2.9 Place the packing list in a document envelope. Seal the envelope and tape to the top of the Styrofoam® container lid.

3.2.10 Close the cardboard shipping box lid and seal with shipping or strapping tape.

3.2.11 Proceed to Step 3.4 for applicable labeling instructions.

3.3. **Packaging Specimens for Shipment With Dry Ice**

Note: Protective gloves must be worn when handling dry ice or other ultra cold products. Avoid inhaling CO_2 vapors from dry ice. Consult the MSDS prior to handling dry ice.

Note: Include a sufficient amount of dry ice to last at least 48 hours.

3.3.1 Follow Steps 3.2.1 to 3.2.4.

3.3.2 Place dry ice in the bottom of the shipping container to at least one quarter of the height of the Styrofoam® shipping container.

3.3.3 Place the sealed secondary package on top of the dry ice in the shipping container.

3.3.4 Fill the shipping container completely with dry ice to cover the secondary packaging(s), ensuring enough room to securely close the lid.

3.3.5 Close the lid to the Styrofoam® shipping container. **Note: Do not seal the Styrofoam® lid with tape. Dry ice vapor must be allowed to vent properly.**

3.3.6 Place the packing list in a document envelope. Seal the envelope and tape to the top of the Styrofoam® container lid.

3.3.7 Close the cardboard shipping box lid and seal with shipping or strapping tape.

3.3.8 Proceed to Step 3.4 for applicable labeling instructions.

3.4. **Labeling of Shipping Container**

Note: No label should wrap around the edge of the container or overlap any other label.

Note: If reusing a shipping container, all labels and markings from the previous shipment shall be removed and/or blackened out with a marker.

The shipping container should be labeled as follows (refer to Appendices II & III):

3.4.1 Place two Biohazard labels at the top right corners on opposing sides of the container.

3.4.2 On the left hand side of one container side, write or label the Shipper's name and address. Write or label the Consignee's name and address below this.

3.4.3 Affix a label identifying the shipment's proper shipping name (i.e., "Biological Substance, Category B, UN 3373" to the right of the Shipper and Consignee information (center of the box).

3.4.4 If shipping with dry ice, place a Dry Ice (CO_2 solid) label (Class 9 Hazard Label; UN1845) below the "Biological Substance, Category B, UN 3373" label.

3.4.5 If orientation markings (i.e., "This Side Up") are not pre-printed on the shipping container, place the orientation labels at the bottom left corners on opposing sides of the container.

3.5. **Shipping By Courier Service**

Note: To minimize the possibility of specimens arriving at WRAIR during the weekend, shipments should be sent out no later than Wednesday (U.S. Eastern Time Zone).

3.5.1 Contact the applicable shipping courier to schedule a pickup.

3.5.2 Complete the shipping courier's airbill as appropriate.

3.5.3 Complete all pertinent documentations (i.e., permits, invoices, declarations, etc.) as required by the applicable country.

3.5.4 Weigh the package and record the total weight in the appropriate space on the courier airbill. If shipping with dry ice, record the approximate amount of dry ice (by weight) in the appropriate space on the courier airbill, and on the Dry Ice (UN1845) label. **Note**: All weight units shall be expressed in kilograms (Kg).

3.5.5 Attach an adhesive plastic pouch, as provided by the courier, to the side or top of the shipping container. **Note**: Do not obscure any of the pertinent labels.

3.5.6 Detach and retain the "Sender's Copy" portion of the airbill. Place the remaining airbill slips, along with other documentations, in the plastic pouch.

3.5.7 Notify the appropriate point of contact at WRAIR (refer to Appendix V), by email, that the shipment is in transit. The body of the email should include the tracking number, the date of shipment, the temperature under which the samples were shipped, and the quantity of specimens. **Note**: Whenever possible, attach a copy of the packing list to the email.

4.0 ABBREVIATIONS AND DEFINITIONS

4.1. Consignee: Shipment receiver or recipient.

4.2. MSDS: Material Safety Data Sheet

4.3. Packing List/Manifest: The packing list or manifest is a document which itemizes in detail the contents of a particular package or shipment. This document may sometimes be referred to as a Sample List.

4.4. Primary Container: The primary container contains the actual sample and must be watertight to prevent leakage. Primary receptacles include those of glass, metal, or plastic and must include screw-cap tubes, or similar closure.

4.5. POC: Point of Contact

4.6. Secondary Container: The primary container is placed inside the secondary container. The secondary container must be watertight and contain the proper absorbent material.

4.7. Shipping Container (outer packaging): The shipping container, must be of adequate strength for its capacity, mass, and intended use, and must be capable of meeting specific UN performance tests. Packages consigned as freight must be at least 100 mm (4 inches) in the smallest overall external dimension. Thus, the outer packaging must be of sufficient size to bear the required markings and labels.

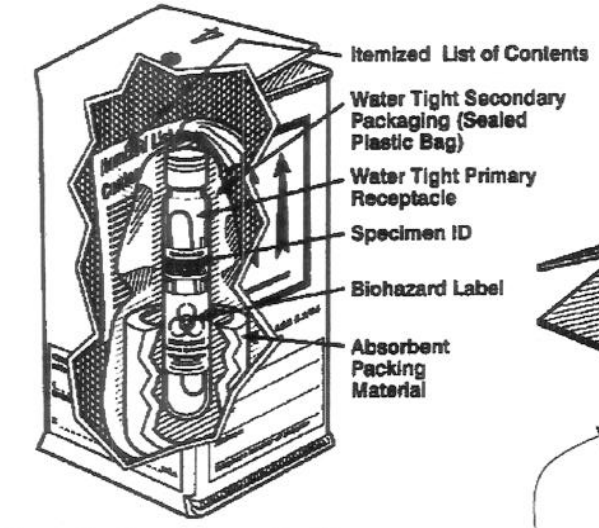
5.0 REFERENCES

5.1. International Air Transport Association (IATA) - *Dangerous Good Regulations (DGR); Packing Instructions – Class 6 – Toxic and Infectious Substances; Packing Instruction 650*

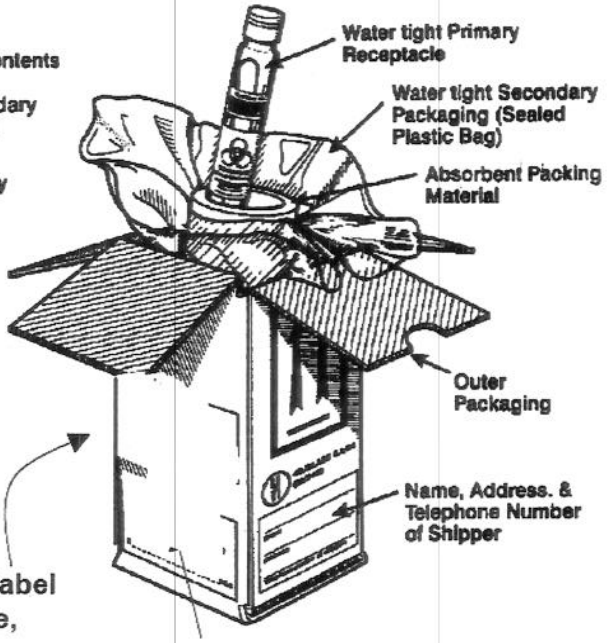
5.2. U.S. Army Center for Health Promotion and Preventive Medicine (USACHPPM) - *Hazardous and Medical Waste Program*

APPENDIX I

Proper Packaging and Labeling Diagram



Cross Section of Proper Packing

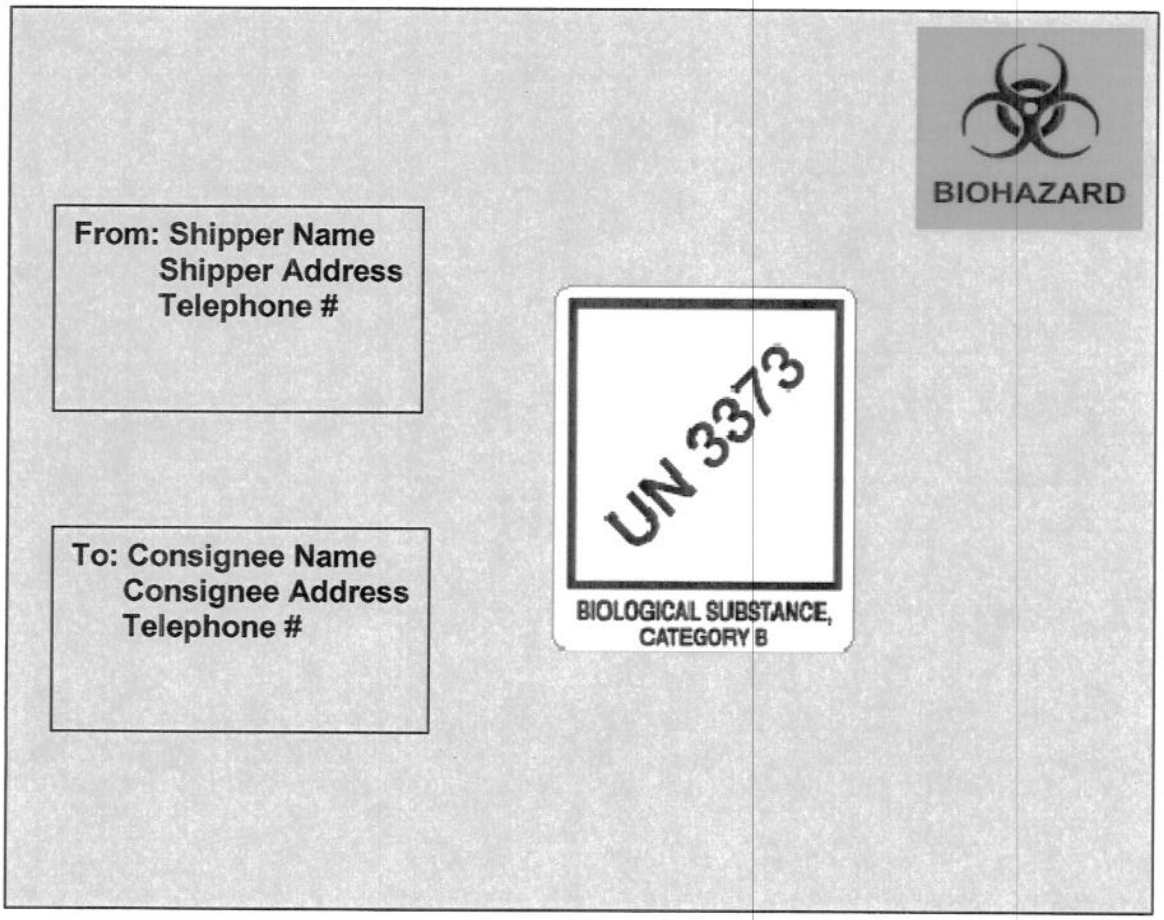


Address label with name, complete shipping

"Diagnostic Specimen UN 3373, Packed

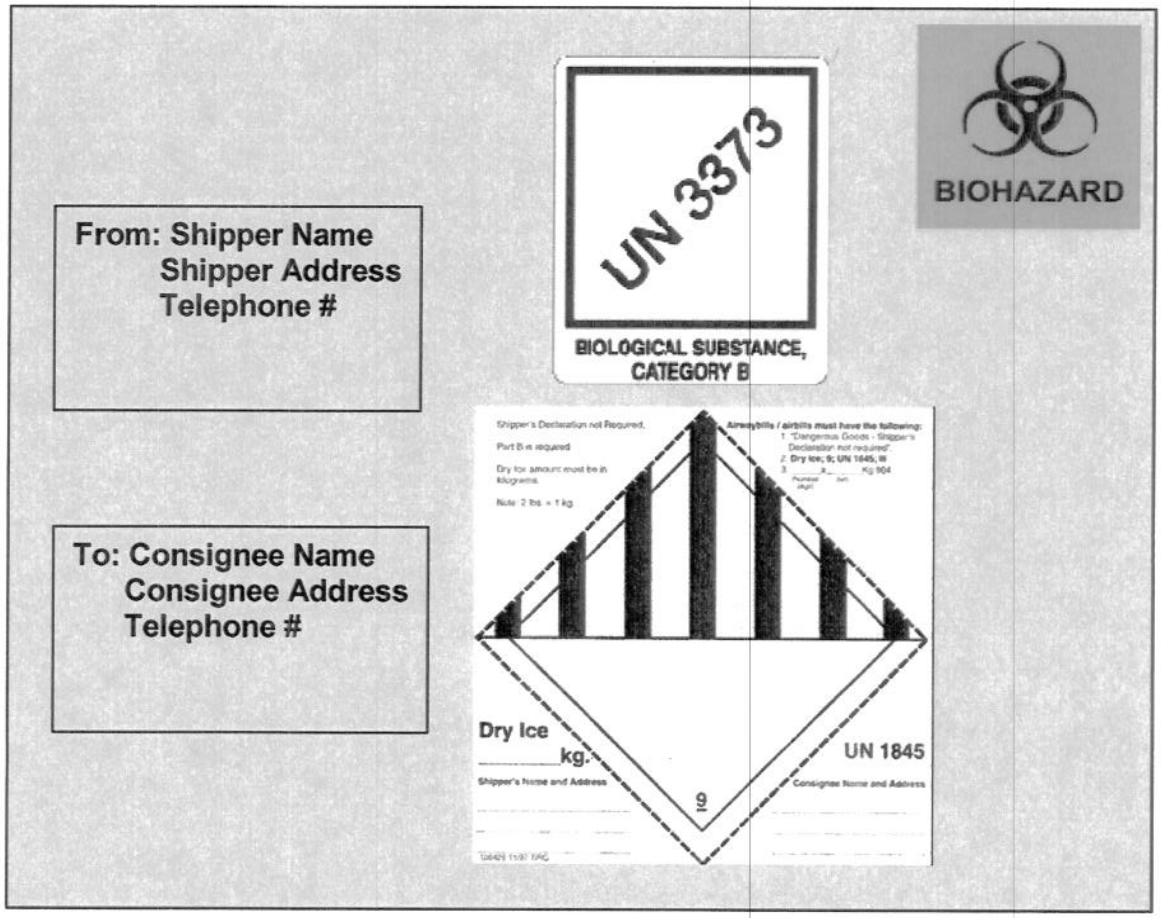
APPENDIX II

Shipping Container Labeling for Shipment at Room Temperature



APPENDIX III

Shipping Container Labeling for Shipment with Dry Ice



APPENDIX IV

Packaging and Labeling of Diagnostic Specimens Check List

Check	Item/Activity
	Packaging
	Screw-caps for all primary receptacles (i.e., specimen collection containers) are secured.
	Primary receptacles are placed upright in the divider in the fiberboard specimen storage box.
	The fiberboard specimen storage box top is secured with tape.
	The specimen storage box is placed inside a leak-proof secondary container (biohazardous bag).
	Absorbent material has been placed in the secondary container (enough absorbent material to absorb the entire contents of all the primary receptacles).
	The secondary container is properly sealed
	DRY ICE SHIPPING ONLY – Dry ice is layered in the bottom of the shipping container to at least on quarter inch.
	The secondary container is placed in the shipping container.
	ROOM TEMP SHIPPING ONLY - Cold packs (kept at room temperature for at least 24 hours) are placed on each side and on top of the secondary container.
	ROOM TEMP SHIPPING ONLY – Shipping container is completely filled with bubble wrap or other cushioning materials.
	DRY ICE SHIPPING ONLY – Shipping container is completely filled with dry ice.
	Styrofoam® container lid is completely closed. **Note**: Do not tape or seal the Styrofoam® lid.
	Document envelope containing packing list is taped to the top of the Styrofoam® container lid.
	Shipping box lid is closed and sealed with shipping or strapping tape.
	Labeling
	Two biohazard labels are placed at the top right corners of opposing sides of the shipping container.
	The Shipper's and Consignee's information (name, address, and phone number) are written/labeled on one side of the container.
	A "Biological Substances, Category B, UN 3373" label is affixed to the right of the Shipper's and Consignee's information.
	DRY ICE SHIPPING ONLY – A dry ice (Class 9, UN1845) label is affixed below the "Biological Substances, Category B, UN 3373" label.
	If not pre-printed, orientation markings (i.e., "This Side Up") are placed on opposite sides of the shipping container.

APPENDIX V

WRAIR Shipping Information

World Courier Account Number – 13248

Primary Consignee POC and Address:

APRIL GRIGGS
WRAIR, DIVISION OF VIRAL DISEASES
503 ROBERT GRANT AVE., BLDG. 503, ROOM 3A04
SILVER SPRING, MARYLAND 20910
USA
(301) 319 – 9732

Alternate Consignee POC and Address:

TUAN NGUYEN
WRAIR, DIVISION OF VIRAL DISEASES
503 ROBERT GRANT AVE., BLDG. 503, ROOM 3A04
SILVER SPRING, MARYLAND 20910
USA
(301) 319 – 9827

Email Addresses:

april.griggs@us.army.mil
tuan.k.nguyen@us.army.mil

APPENDIX VI

IATA Packing Instruction 650

Packing Instructions — Class 6 — Toxic and Infectious Substances

PACKING INSTRUCTION 650

STATE VARIATIONS: BHG-02 CAG-05 DQG-03 FRG-06 GBG-05 VCG-04

△ OPERATOR VARIATIONS: AF-02 AM-06 AM-10 AS-08 BR-14 CI-01 CO-07 CS-07 FX-09 IJ-06 IJ-10 JJ-06 JK-03 KE-06 LA-07 LH-12 MN-03 MS-03 MX-06 MX-11 OO-01 OU-12 OU-16 PX-08 SQ-10 TK-08 TY-03 UA-14 UU-05 XK-05

This instruction applies to UN 3373 on passenger and cargo aircraft and CAO.

General Requirements

The packagings must be of good quality, strong enough to withstand the shocks and loadings normally encountered during transport, including trans-shipment between transport units and between transport units and warehouses as well as any removal from a pallet or overpack for subsequent manual or mechanical handling. Packagings must be constructed and closed so as to prevent any loss of contents that might be caused under normal conditions of transport, by vibration, or by changes in temperature, humidity or pressure.

The packaging must consist of three components:

(a) a primary receptacle(s);
(b) a secondary packaging; and
(c) a rigid outer packaging.

Primary receptacles must be packed in secondary packagings in such a way that, under normal conditions of transport, they cannot break, be punctured or leak their contents into the secondary packaging. Secondary packagings must be secured in outer packagings with suitable cushioning material. Any leakage of the contents must not compromise the integrity of the cushioning material or of the outer packaging.

Packages must be prepared as follows:

(a) For liquid substances:

- The primary receptacle(s) must be leakproof and must not contain more than 1 L;
- The secondary packaging must be leakproof;
- If multiple fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent contact between them;
- Absorbent material must be placed between the primary receptacle and the secondary packaging. The absorbent material, such as cotton wool, must be in sufficient quantity to absorb the entire contents of the

primary receptacle(s) so that any release of the liquid substance will not compromise the integrity of the cushioning material or of the outer packaging;

- The primary receptacle or the secondary packaging must be capable of withstanding, without leakage, an internal pressure of 95 kPa in the range of -40°C to 55°C (-40°F to 130°F).

  Note:
  The capability of a packaging to withstand an internal pressure without leakage that produces the specified pressure differential should be determined by testing samples of primary receptacles or secondary packagings. Pressure differential is the difference between the pressure exerted on the inside of the receptacle or packaging and the pressure on the outside. The appropriate test method should be selected based on receptacle or packaging type. Acceptable test methods include any method that produces the required pressure differential between the inside and outside of a primary receptacle or a secondary packaging. The test may be conducted using internal hydraulic or pneumatic pressure (gauge) or external vaccum test methods. Internal hydraulic or pneumatic pressure can be applied in most cases as the required pressure differential can be achieved under most circumstances. An external vacuum test is not acceptable if the specified pressure differential is not achieved and maintained. The external vacuum test is a generally acceptable method for rigid receptacles and packagings but is not normally acceptable for

  – flexible receptacles and flexible packagings
  – receptacles and packagings filled and closed under a absolute atmospheric pressure lower than 95 kPa

- The outer packaging must not contain more than 4 L. This quantity excludes ice, dry ice or liquid nitrogen when used to keep specimens cold.

(b) For solid substances:

- The primary receptacle(s) must be siftproof and must not exceed the outer packaging weight limit;
- The secondary packaging must be siftproof;
- If multiple fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent contact between them;
- Except for packages containing body parts, organs or whole bodies, the outer packaging must not contain more than 4 kg. This quantity excludes ice, dry ice or liquid nitrogen when used to keep specimens cold;
- If there is any doubt as to whether or not residual liquid may be present in the primary receptacle during transport then a packaging suitable for liquids, including absorbent materials, must be used.

⌯An itemized list of contents must be enclosed between the secondary packaging and the outer packaging.

At least one surface of the outer packaging must have a minimum dimension of 100 mm x 100 mm (4 in x 4 in).

△The completed package must be capable of successfully passing the drop test described in 6.5.1.1 except that the height of the drop must not be less than 1.2 m. Following the appropriate drop sequence, there must be no leakage from the primary receptacle(s) which must remain protected by absorbent material, when required, in the secondary packaging.

For transport, the mark illustrated below must be displayed on the external surface of the outer packaging on a background of a contrasting colour and must be clearly visible and legible. The mark must be in the form of a square set at an angle of 45°(diamond-shaped) with each side having a length of at least 50 mm (2 in), the width of the line must be at least 2 mm and the letters and numbers must be at least 6 mm high. The proper shipping name "Biological Substance, Category B" in letters at least 6 mm high must be marked on the outer package adjacent to the diamond-shaped mark.

Unless all package markings are clearly visible, the following conditions apply when packages are placed in an overpack:

- the overpack must be marked with the word "Overpack"; and
- the package markings must be reproduced on the outside of the overpack.

A Shipper's Declaration for Dangerous Goods is not required.

Specific Requirements

Refrigerated or frozen specimens: Ice, dry ice and liquid nitrogen:

- When dry ice or liquid nitrogen is used to keep specimens cold, all applicable requirements of these Regulations must be met. When used, ice or dry ice must be placed outside the secondary packagings or in the outer packaging or an overpack. Interior supports must be provided to secure the secondary packagings in the original position after the ice or dry ice has dissipated. If ice is used, the outside packaging or overpack must be leakproof. If dry ice is used, the packaging must be designed and constructed to permit the release of carbon dioxide gas to prevent a build-up of pressure that could rupture the packagings.
- The primary receptacle and the secondary packaging must maintain their integrity at the temperature of the refrigerant used as well as the temperatures and the pressures, which could result if refrigeration were to be lost.

Infectious substances assigned to UN 3373 which are packed and marked in accordance with this packing instruction are not subject to any other requirement of these Regulations except for the following:

(a) the name and address of the shipper and of the consignee must be provided on each package;

(b) the name, and telephone number of a person responsible must be provided on the air waybill or on the package;

(c) the classification must be in accordance to 3.6.2;

(d) the incident reporting requirements in 9.6.1 must be met; and

(e) the inspection for damage or leakage requirements in 9.4.1 and 9.4.2.

Note:
When the shipper or consignee is also the 'person responsible' as referred to in b) above, the name and address need be marked only once in order to satisfy the name and address marking provisions in both a) and b), above.

Passengers and crew members are prohibited from transporting infectious substances as or in carry-on baggage, checked baggage or on their person.

△⇐ If an Air Waybill is used, the "Nature and Quantity of Goods" box should show "UN 3373" and the text "BIOLOGICAL SUBSTANCE, CATEGORY B".

Clear instructions on filling and closing such packages must be provided by packaging manufacturers and subsequent distributors to the shipper or to the person who prepares the package (e.g. patient) to enable the package to be correctly prepared for transport.

Other dangerous goods must not be packed in the same packaging as Division 6.2 Infectious Substances unless they are necessary for maintaining the viability, stabilizing or preventing degradation or neutralizing the hazards of the infectious substances. A quantity of 30 mL or less of dangerous goods included in Classes 3, 8 or 9 may be packed in each primary receptacle containing infectious substances provided these substances meet the requirements of 2.7.1 and 2.7.5. When these small quantities of dangerous goods are packed with infectious substances in accordance with this packing instruction, no other requirements in these Regulations need be met.